#### DENTAL BOARD OF CALIFORNIA

#### INITIAL STATEMENT OF REASONS

Hearing Date: May 31, 2006

Subject Matter of Proposed Regulations: Oral Conscious Sedation (OCS)

Sections Affected: 1044, 1044.1, 1044.2, 1044.3, 1044.4, 1044.5, 1044.6

Specific Purpose of each adoption, amendment, or repeal:

The proposed amendments to Sections 1044 et seq. are a result of the passage of AB 1386, Chapter 539, 2005, effective January 1, 2006. This bill adds to the Dental Practice Act a provision that a dentist must hold a valid adult oral conscious sedation (OCS) certificate in order to administer oral conscious sedation to adult patients. Additional amendments are based on discussions by the Board regarding current practice and standards of patient care during the administration of oral conscious sedation to both minors and adults. References are updated throughout to reflect the current statute. See below for more details.

## 1044

The Articles are amended to reflect the new statute.

- (a) Existing language is amended to specify facilities referred to in statute and the obsolete reference to a patient under the age of 13 is eliminated. Existing language which references "an accrediting entity approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 (commencing with section 1248) is removed as these are outpatient facilities and exempting them would be contrary to the statute.
- (b) This language is removed as it is duplicated in 1044.5(c)(1)
- (c) Defines the term "age-appropriate", which is necessary to distinguish between the requirements of sedation for minors and those for adults throughout the Section. This is necessary due to the new statutory requirement that a certificate is required to administer oral conscious sedation to either minor patients or adult patients after January 1, 2006.

Note: There is a Reference citation change to include the new statutory sections of law.

### 1044.1

Existing language is amended to specify who may administer oral conscious sedation and whether to adults or minors, since current language only provides for oral conscious sedation administration to minor patients. New language is added to clarify the statutory provisions of Sections 1647.19 and 1647.20 relative to Sections 1647.10, 1647.11 and 1647.12 that a dentist who holds an oral conscious sedation certificate for adults is not

permitted to administer oral conscious sedation to minors, since the standard of care is different for a minor child than for an adult patient. There is also a Reference citation change to include the new statutory sections of law.

### 1044.2

"Periodontology residency" is added to specify a qualified program. Existing regulations do not specify the required educational training, and including the "Commission on Dental Accreditation (CODA)" provides clarification that the board will accept a program approved by this organization. Language is added to specify that evidence of completion must be submitted to the board, which is not currently in the regulation. There is also a Reference citation change to include the new statutory sections of law.

# <u>1044.3</u>

- (a) The new provisions of AB 1386 require that a licensee must obtain a certificate to administer oral conscious sedation to adults. This amendment adds the term "or adult" to conform the Section to the new statute.
- (b) The phrase "in a facility" is deleted because educational programs are approved by the board, facilities are not. The term "age-appropriate" is added throughout to clarify the distinction of certification programs allowing administration of oral conscious sedation to minor dental patients from those that relate to adult dental patients.
- (c) And (d) These amendments are nonsubstantive changes that eliminate the capital "b" from the word board and correct the revision date of the required form.

Note: There is a Reference citation change to include the new statutory sections of law.

## <u>1044.4</u>

AB 1386, Chapter 539, 1647.20, requires the addition of new language to this section to make specific the new statutory requirements which allow a dentist who has been using oral conscious sedation in the treatment of adult patients to be certified.

- (a) This new language is added to specify that a certificate may be granted to a licensee who has been using oral conscious sedation in connection with the treatment of adult patients in their practice based upon submission of a form documenting 10 cases of treatment.
  - Items (1) (6) This new language specifies the information that the applicant must submit on the form to enable the reviewer to confirm that the applicant successfully administered oral conscious sedation on the required number of patients.
- (b) This new language specifies the content of the documentation required for an applicant to become certified to administer oral conscious sedation to adults, including: patient information, the date of the procedure, the type of procedure, the method, amount and specific oral conscious sedation agent used, how the patient was monitored and by

- whom, and the patient's condition at discharge. The reviewer uses this information to verify the applicant's qualifications for certification.
- (c) This new language specifies the format in which the required information must be submitted, ensuring that identifying patient information is removed to protect each patient's privacy.

Note: There is a Reference citation change to include the new statutory sections of law.

### 1044.5

The new statute requires oral conscious sedation certification for treatment of adult patients as well as minor patients according to the provisions of AB 1386; therefore, the term "minor" is removed from existing language.

- (a)(5) Existing language is amended by removal of the terms "minor and "ages" and replacement with the term "age-appropriate" to include equipment specifications for adult patients according to the provisions of AB 1386.
- (a)(6) Existing language is amended by removal of the term "minor" and replacement with the term "age-appropriate" to include equipment specifications for adult patients according to the provisions of AB 1386.
- (b)(1) and (2) Existing language is amended by removal of the terms "minor and "ages" and replacement with the term "age-appropriate" to include ancillary equipment specifications for adult patients according to the provisions of AB 1386.
- (c) (1) The amendments include additional requirements as to information must be in a patient's medical history and physical evaluation records to conform to the current standard of care to ensure patient safety. The term "minor" is removed and new language pertaining to adult patients is added according to the provisions of AB 1386.
- (d) Existing language is amended by removing the term "minor" to clarify that the Section applies to adult patients as well as minors, due to the provisions of AB 1386.
- (d)(1) This amendment replaces the existing generic drug category, "vasopressor," with Epinephrine, the specific drug of standard usage in emergency situations, for patient safety.
- (d)(2) This amendment removes the existing drug "corticosteroid," which is a slow-acting agent no longer considered to be useful in an emergency setting, for patient safety.

Note: There is a Reference citation change to include the new statutory sections of law.

#### Factual Basis:

AB 1386 was passed in October 2005, necessitating amendments to the Section and the addition of Section 1044.4. These amendments increase patient safety during the procedure and distinguish between the requirements for administering conscious sedation

to minors from those for adults. Prior to passage of AB 1386, a dentist was not required to hold a certificate to administer oral conscious sedation (OCS) to adult patients.

Language is added to Section 1044.4 to specify the requirements of AB 1386 that allow a dentist to be certified to administer OCS to adult patients based upon documentation of ten successful cases of treatment. Also, a panel of experts in the anesthesia field issued a report whose findings were brought to the Board on November 3, 2003. Those findings were discussed and, over the course of the past two years at several Board committee meetings, were developed into amendments to existing regulatory language to increase patient safety and update it to the current standard of care. Those amendments are included.

# **Underlying Data**

- 1. AB 1386, Chapter 539, October 5, 2005.
- 2. Recommendations from the Blue Ribbon Panel on Anesthesia, November 7, 2003.
- 3. Minutes from General Anesthesia Committee, November 4, 2004.
- 4. Minutes from Dental Board Meeting, November 5, 2004.
- 5. American Academy of Periodontology Report: Guidelines, In-Office Use of Conscious Sedation in Periodontics, April 2001.
- American Academy of Pediatric Dentistry, Clinical Guideline on the Elective Use of Minimal, Moderate and Deep Sedation and General Anesthesia for Pediatric Dental Patients, Revised 2004.
- 7. American Association of Oral and Maxillofacial Surgeons: Parameters and Pathways: Clinical Practice Guidelines for Oral and Maxillofacial Surgery (AAOMS ParPath01), Anesthesia in Outpatient Facilities, Version 3.0, 2001.
- 8. American Association of Oral and Maxillofacial Surgeons: Parameters and Pathways: Clinical Practice Guidelines for Oral and Maxillofacial Surgery (AAOMS ParPath01), Patient Assessment, Version 3.0, 2001.
- 9. American Dental Association Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists, October 2003
- 10. Dental Board of California, Dental Patient Mortalities Related to General Anesthesia/Conscious Sedation/Oral Anesthesia, 1/22/01.

## **Business Impact:**

This regulation will not have a significant adverse economic impact on businesses.

## Specific Technologies or Equipment

This regulation mandates the use of specific technologies and equipment that are required for patient safety during the administration of oral conscious sedation.

# **Consideration of Alternatives**

No alternatives that were considered were determined to provide the appropriate level of public protection for adult patients and minor patients undergoing oral conscious sedation as the proposed regulations.